MERBARONE

NSC - 336628

Chemical Name: Hexahydro-4,6-dioxo-<u>N</u>-phenyl-2-thioxo-5-pyrimidinecarboxamide

Other Name: 5-Carboxyanilino-2-thiobarbituric acid

CAS Registry Number: 97534-21-9

Molecular Formula: $C_{11}H_9N_3O_3S$ M.W.: 263.3

How Supplied: For injection, 200 mg, vial: supplied as a lyophilized powder with 400 mg meglumine in 30 mL amber vials.

Solution Preparation: 200 mg/vial: When constituted with 19.5 mL of Sterile Water for Injection, USP, each milliliter contains 10 mg of merbarone with 20 mg of meglumine at pH 9 to 10.

The solution may be light yellow, peach-colored, or light pink in color.

Storage: Refrigerate the intact vials (2-8 °C) and protect from light.

Stability: Shelf-life surveillance of the intact vials is ongoing. The intact vials are stable for 5 years at room temperature (22-25 °C). The intact vials are stable for at least one year at elevated temperature (50 °C).

Constitution as directed results in a solution which is stable for 15 days at room temperature.

Further dilution to a concentration of 0.1 mg/mL with 5% Dextrose Injection, USP, in glass or PVC plastic containers also results in a solution exhibiting little or no decomposition after two weeks of storage at 0 °C, room temperature, and 37 °C.

Merbarone is incompatible with metal ions such as Na⁺,K⁺,Ca⁺⁺, and Mg⁺⁺. A precipitate may form if the drug is diluted in solutions containing these ions. Dilution of merbarone with isotonic sodium chloride solution has resulted in the formation of crystals in 30 minutes. Therefore, merbarone should not be diluted with solutions which contain metal ions.

CAUTION: This single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous